

**Omega-3-Acid Ethyl Esters (Lovaza® and Omtryg®), Icosapent Ethyl (Vascepa®), Omega-3-Carboxylic Acids (Epanova®)**

**Criteria for Use**

March 2015

VHA Pharmacy Benefits Management Services, Medical Advisory Panel and VISN Pharmacist Executives

*The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD UTILIZE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.*

*The Product Information should be consulted for detailed prescribing information.*

See the VA National PBM-MAP-VPE Monographs on these drugs at [www.pbm.va.gov](http://www.pbm.va.gov) or <https://vaww.cmopnational.va.gov/cmop/PBM/default.aspx> for further information.

Lovaza®, Omtryg®, Epanova® and Vascepa® are approved as an adjunct to diet in patients with very high triglyceride (TG) levels ( $\geq 500$  mg/dL).

**Inclusion Criteria All boxes must be checked in order to meet criteria to receive either drug**

- ☐ Patients with TG Levels  $\geq 500$  mg/dL

**AND**

- ☐ Inadequate TG lowering response to a therapeutic trial of formulary fish oil or an inability to take 8 fish oils capsules daily.\*

**The effect of Lovaza, Omtryg, Epanova or Vascepa on cardiovascular morbidity or mortality or on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been established.**

\*1 capsule of Lovaza = 1 gram DHA+EPA; \*1 capsule of Omtryg = 900 mg EPA+DHA; \*1 capsule of Epanova = ~850 mg EPA+DHA; 1 capsule of Vascepa = 1 gram of EPA; 1 capsule of formulary fish oil = 0.5 grams DHA+EPA

**Recommendations: Prior to initiating drug therapy for hypertriglyceridemia**

- ☐ Institute therapeutic lifestyle changes (e.g. cessation of alcohol, weight loss, initiation of lipid-lowering diet, including elimination of sugar-sweetened beverages, and exercise)

**AND**

- ☐ Address secondary causes of hypertriglyceridemia (e.g. poorly controlled diabetes mellitus, nephrotic syndrome, alcoholism, hypothyroidism, high intake of sugar sweetened beverages and medications (Especially protease inhibitors. Others may include corticosteroids, estrogens, beta-blockers and thiazide diuretics).

Updated versions may be found at <http://vaww.pbm.va.gov> or <http://www.pbm.va.gov>  
February 2006, Revised September 2007-trade name change only; Revised 3-2014 to include icosapent ethyl and to remove requirement to use niacin and/or fibrate prior to fish oil. Revised February 2015 to include Omtryg and Epanova)

**Omega-3 acid ethyl esters/Icosapent Ethyl/  
Omega-3-Carboxylic Acids  
Criteria for NF Use**

<b>Dosing</b>
For patients with TG levels $\geq 500$ mg/dL, the dose of Lovaza or Omtryg is 4 grams daily given as 4 capsules once daily or 2 capsules twice daily with a meal. For Epanova, the dose is 2 or 4 grams once daily without regard to meals. For Vascepa, the dose is 4 grams daily given as 2 capsules twice daily capsules with food.
<b>Monitoring</b>
<ul style="list-style-type: none"> <li>❑ TGs should be monitored within 8 weeks of initiation of Lovaza, Omtryg, Epanova or Vascepa and then periodically to determine response to treatment.</li> <li>❑ ALT and AST should be monitored periodically in patients with hepatic impairment. ALT was observed to increase with a concurrent increase in AST in some patients during Lovaza or Vascepa therapy.</li> <li>❑ Although data are inconclusive on the interaction and risk for bleeding between fish oils and warfarin or other drugs affecting coagulation, close monitoring is recommended in these patients.</li> </ul>
<b>Discontinuation of Lovaza® or Vascepa® or Omtryg® or Epanova®</b>
Lovaza, Omtryg, Epanova or Vascepa should be discontinued if an adequate TG lowering response (20-30%) has not been observed within 2 months of treatment.

ALT=Alanine aminotransferase, AST=aspartate aminotransferase, EPA=eicosapentaenoic acid, DHA=docosahexaenoic acid, TG=triglyceride